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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/048,212	06/07/2002	Atsushi Miyamoto	Q68293	4780
23373 7590 08/11/2008 SUGHRUE MION, PLLC 2100 PENNSYLVANIA AVENUE, N.W. SUITE 800 WASHINGTON, DC 20037			EXAMINER COOK, LISA V	
			ART UNIT 1641	PAPER NUMBER
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/048,212

Applicant(s)

MIYAMOTO ET AL.

Examiner

LISA V. COOK

Art Unit

1641

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 May 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1, 4-6, 9 and 10 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 4-6, 9 and 10 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-8508)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Amendment Entry

1. Applicants response to the Non-Final Office Action mailed 25 January 2008 is acknowledged (Paper filed 5/27/08). In the amendment filed therein, claims numbered 1 and 6 were modified. Claims 2, 3, 7, and 8 have been canceled without prejudice or disclaimer. Currently, claims 1, 4-6, and 9-10 are pending and under consideration.
2. Objections and/or rejection of record not reiterated herein have been withdrawn.

NEW GROUNDS OF REJECTIONS

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

I. Claims 1, 4, 6, and 9 are rejected under 35 U.S.C.103(a) as being unpatentable over Fujimoto Eiki et al. (11-023573, English Translation) in view of Dosa et al. (Immunology, 1979, 38, pages 509-517) and further in view of Scherr (US Patent #4,096,138).

Fujimoto Eiki et al. teach agglutination procedures to measure antibody-antigen binding. In the procedure two reagents are prepared and utilized to measure an analyte of interest. One reagent is heat denatured albumin. Please see sections 0009 and 0023. The reaction procedure includes BSA, thermal-denatured (denaturation) bovine serum albumin, and antigen (i.e. TP antigen support latex suspension). See sections 0034-0039. This agglutination process is taught to inhibit nonspecific reaction and is simple. See sections 0001, 0032, and 0042.

Although Fujimoto Eiki et al. disclose BSA denaturation by heat (thermal), they are silent with respect to protease treatment (pepsin digest) to produce fragmented BSA. However, Dosa et al. disclose the effect of peptic degradation on the immunological and antigenic properties of bovine serum albumin (BSA). See abstract. BSA was digested with pepsin and the fluorescence-binding efficiency evaluated. The BSA fragments obtained from a digest did not form BSA-anti-BSA immune complexes (see page 511-512) and did not interact with B cells (see page 516, 1st column 1st paragraph).

The systematic degradation of BSA with pepsin provided an excellent model for investigating the function and nature of different antigenic determinants present on protein antigens. Page 515, 2nd column – Discussion.

Fujimoto Eiki et al. discloses the claimed invention except for the fragmented BSA produced from pepsin digestion (protease treatment).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to degrade BSA with pepsin thereby producing fragmented BSA because Dosa et al. taught that the systematic degradation of BSA with pepsin provided an excellent model for investigating the function and nature of different antigenic determinants present on protein antigens. Page 515, 2nd column – Discussion.

Fujimoto Eiki et al. in view of Dosa et al. differ from the instant invention in not specifically teaching the utility of BSA coated latex particles carrying an antibody or antigen specifically reactive with the analyte of interest.

Scherr teach this limitation. Specifically, Scherr disclose immunological test procedures. The agglutination tests involving proteins coupled to particles. See column 1 lines 24-43. The use of BSA coated surfaces is taught to eliminate spatial interference due to steric hindrance. See column 2 lines 38-68.

It would have been prima facie obvious to one of ordinary skill in the art at the time of applicant's invention to use a BSA coated latex assay as taught by Sherr with the BSA protease pre-treatment method of Fujimoto Eiki et al. in view of Dosa et al. because Sherr taught that the use of BSA coated surfaces eliminated spatial interference due to steric hindrance. See column 2 lines 38-68.

One of ordinary skill in the art would have been motivated to use BSA coated latex in order to reduce interferences.

II. Claims 5 and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fujimoto Eiki et al. (11-023573, English Translation) in view of Dosa et al. (Immunology, 1979, 38, pages 509-517) and further in view of Scherr (US Patent #4,096,138) as applied to claims 1, 4, 6, and 9 above, and further in view of Nakase et al. (JP 48019719 Abstract Only).

Please see Fujimoto Eiki et al. (11-023573, English Translation) in view of Dosa et al. and further in view of Scherr as set forth above. Fujimoto Eiki et al. (11-023573, English Translation) in view of Dosa et al. and further in view of Scherr. disclose the reagent combination involving protease treatment in combination with BSA and antigen/antibody coated BSA latex particles. However, Fujimoto Eiki et al. (11-023573, English Translation) in view of Dosa et al. and further in view of Scherr do not teach the use of these reagents for anti-streptolysin O antibodies.

Nakase et al. disclose that the addition of BSA (bovine serum albumin) to streptolysin O stabilizes streptolysin O and allows streptolysin O to maintain its activity. See abstract.

Therefore, it would have been prima facie obvious to one of ordinary skill in the art at the time of applicant's invention to take the protease treatment in combination with BSA and antigen/antibody coated latex particles detection reagents as taught by Fujimoto Eiki et al. (11-023573, English Translation) in view of Dosa et al. and further in view of Scherr and utilize them in turbidity measurements for anti-streptolysin O antibodies/antigen assays because Nakase et al. disclose that the addition of BSA (bovine serum albumin) to streptolysin O stabilizes streptolysin O and allow streptolysin O to maintain its activity. See abstract.

Response to Arguments

Applicant's arguments and amendments have overcome the rejections of record. However, new rejections are presented herein. Therefore the prior art reads on the instant claims.

4. For reasons aforementioned, no claims are allowed.

Remarks

5. Prior art made of record and not relied upon is considered pertinent to the applicant's disclosure:

A. Masson et al. (EPO 0 061 857 A1) disclose pepsin digestion to eliminate protein interferences. See page 8 lines 25 through 30.

6. Papers related to this application may be submitted to Group 1600 by facsimile transmission. The Group 1641 – Central Fax number is (571) 273-8300, which is able to receive transmissions 24 hours/day, 7 days/week. In the event Applicant would like to fax an unofficial communication, the Examiner should be contacted for the appropriate Right Fax number.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lisa V. Cook whose telephone number is (571) 272-0816. The examiner can normally be reached on Monday - Friday from 7:00 AM - 4:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mark Shibuya, can be reached on (571) 272-0806.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group TC 1600 whose telephone number is (571) 272-1600.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR.

Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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8/6/08

/Lisa V. Cook/
Examiner, Art Unit 1641